DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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MAY 24 2002

Mr. Cheng Lin-Hui Chiang
President
Maxluck Biotechnology Corporation
10F, No. 75-1, Sung Jiang Road
Zhong Shan District
Taipei, Taiwan
Republic of China

Dear Mr. Chiang:

This is in response to your letter to the Food and Drug Administration (FDA) dated April 17, 2002. Your letter was submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Maxluck Biotechnology Corporation is making the claims identified below for the product **GT&F NutriPack** which it intends to market as a dietary supplement:

> "Dietary Supplement for a Healthy Glucose Metabolism."
> "GT&F NutriPack is a specially formulated dry powdered product for making beverages. A consistent use of this product will support in keeping blood glucose at a healthy level."

Your submission also states that "This product is intended to be used as a beverage by adult [sic] over the age of 18 to maintain a healthy glucose metabolism."

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). In your submission, you state that the intended use of GT&F NutriPack is, in part, as a powdered product for making beverages. Beverages are conventional foods. Given this representation for the product's intended use, GT&F NutriPack is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, GT&F NutriPack is a beverage and, therefore, a conventional food and it must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, GT&F NutriPack must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the

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product in its labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to market GT&F NutriPack as a beverage and you have any questions about the status of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 200 C St., SW, Washington, DC 20204.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

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Office of Special Nutritions)HFX-450)
Center for Food Safty and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

George Su
C/O Maxluck Biotechnology Corporation
Crosslinks International, Inc.
1800 Century Park East, Suite 600
Century City, CA 90067

Product: **GT&F NutriPack**

This is a notice to the person or persons or company who submitted the Notification Letter for State ment on Dietary Supplement of the above product.

This office has received the submission and filed the Notification Letter as per Code of Federal Regulations, Vol. 21, Part 101.93.

Sincerely,

Name:
Position:
Date:

MAXLUCK BIOTECHNOLOGY CORPORATION

Office of Special Nutritionals (HFX-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parekway
College Park, MD 20740-3835

April 17, 2002

Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of Maxluck Biotechnology Corporation, who is, among other things, a manufacturer and distributor of dietary supplements in Taiwan, Republic of China. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label and in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

   This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

   Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

   Maxluck Biotechnology Corporation

   10F, No. 75-1, Sung Jiang Road
   Zhong Shan District, Taipei
   Taiwan
   R. O. C.

Tel: 886-2-2518-9908
Fax: 886-2-2518-9918

The telephone number for consumer inquiries in the U.S. is:

Tel: 626-350-8889

3. Product Identification:
The trade name of the product:

GT&F NutriPack

The common and usual name of the product:

None

A label copy showing all information displayed and provided to consumers is attached.

4. The text of the Structure/Function Statement:

Dietary Supplement for a Healthy Glucose Metabolism

GT&F NutriPack is a specially formulated dry powdered product for making beverages. A consistent use of this product will support in keeping blood glucose at a healthy level.

5. Ingredient Statement

This product is a proprietary blend of milk powder dairy ingredients, blended flour and minerals. The following is a complete list of dietary ingredients:

Milk Powder, rice flour, blended flour (oat flour, buckwheat flour, bob's tears seed flour), dietary fiber, starch, aspartame**, chromium (III) chloride.
** Phenylketonurics: Contains phenylalanine.

6. Intended Use:

This product is intended to be used as a beverage by adult over the age of 18 to maintain a healthy glucose metabolism.

Dosage: One sachet (35 g) twice daily.

Warning: Not recommended for persons under the age of 18. Consult your physician if you are on any type of medication. Should you have any question, regarding the use of this product, please consult your doctor or call the